



11-22--04

IPD

Attorney's Docket No.: 16743-003001 / 12A-920716

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Chen, et al. Art Unit : 1614
Serial No. : 10/705,245 Examiner : Unknown
Filed : November 10, 2003
Title : RISK ASSESSMENT FOR ADVERSE DRUG REACTIONS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

Articles

1. Chung, W.H., et al. (2004). Medical genetics: a marker for Stevens-Johnson syndrome. *Nature*. 428(6982):486.
2. Gumperz, J.E., et al. (1995). The Bw4 public epitope of HLA-B molecules confers reactivity with natural killer cell clones that express NKB1, a putative HLA receptor. *J Exp Med*. 181(3):1133-1144.
3. Gut, J. (2002). Severe adverse drug reactions and theragenomics. *Business Briefing Pharmatech*. Retrieved from the Internet: [URL: http://therastrat.com/downloads/Gut_2002_Servere_Adverse_Drug_Reactions.pdf](http://therastrat.com/downloads/Gut_2002_Servere_Adverse_Drug_Reactions.pdf) retrieved on 2004-10-01.
4. Hildesheim, A., et al. (2002). Association of HLA class I and II alleles and extended haplotypes with nasopharyngeal carcinoma in Taiwan. *J Natl Cancer Inst*. 94(23):1780-1789.
5. Mallal, S. et al. (2002). Association between presence of HLA-B*5701, HLA-DR7, and HLA-DQ3 and hypersensitivity to HIV-1 reverse-transcriptase inhibitor abacavir. *Lancet*. 359(9308):727-732.

CERTIFICATE OF MAILING BY EXPRESS MAIL

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November 18, 2004

Date of Deposit

6. Nassif, A., et al. (2002). Drug specific cytotoxic T-cells in the skin lesions of a patient with toxic epidermal necrolysis. *J Invest Dermatol.* 118(4):728-733.
7. Pirmohamed, M., and Park, B.K. (2003). Adverse drug reactions: back to the future. *Br J Clin Pharmacol.* 55(5):486-492.
8. Romphruk, A., et al. (2003). HLA-B*15 subtypes in the population of north-eastern Thailand. *Eur J Immunogenet.* 30(2):153-158.

These documents are being submitted before a first Office Action on the merits, therefore no fee is required under 37 C.F.R. § 1.97(b). In the event an Office Action is mailed by the United States Patent and Trademark Office prior to receipt of this Information Disclosure Statement, Applicants hereby make the statement specified in 37 C.F.R. §1.97(e) that each document contained herein was first cited in the International Search Report for the corresponding PCT application (PCT/US2004/019435) within three (3) months of the filing date of this Supplemental Information Disclosure Statement. Therefore, no fee is required under 37 C.F.R. § 1.97(c). A copy of this International Search Report is also enclosed herewith.

For the purpose of patent term adjustment, Applicants also wish to point out that this Supplemental Information Disclosure Statement is being filed within 30 days of receipt of the aforementioned International Search Report by Applicants or Applicants' representatives.

By citing the above references, Applicants do not acquiesce or admit that any of these documents is "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

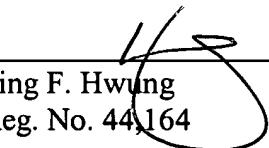
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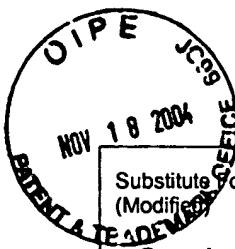
Respectfully submitted,

Date: November, 2004


Ping F. Hwung
Reg. No. 44,164

Fish & Richardson P.C.
500 Arguello Street, Suite 500
Redwood City, California 94063
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16743-003001 / 12A-920716	Application No. 10/705,245
Supplemental Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Chen, et al.	
		Filing Date November 10, 2003	Group Art Unit 1614

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA						
	AB						
	AC						

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AD							
	AE							
	AF							

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AG	Chung, W.H., et al. (2004). Medical genetics: a marker for Stevens-Johnson syndrome. Nature. 428(6982):486.
	AH	Gumperz, J.E., et al. (1995). The Bw4 public epitope of HLA-B molecules confers reactivity with natural killer cell clones that express NKB1, a putative HLA receptor. J Exp Med. 181(3):1133-1144.
	AI	Gut, J. (2002). Severe adverse drug reactions and theragenomics. Business Briefing Pharmatech. Retrieved from the Internet: URL: http://therastrat.com/downloads/Gut_2002_Servere_Adverse_Drug_Reactions.pdf retrieved on 2004-10-01.
	AJ	Hildesheim, A., et al. (2002). Association of HLA class I and II alleles and extended haplotypes with nasopharyngeal carcinoma in Taiwan. J Natl Cancer Inst. 94(23):1780-1789.
	AK	Mallal, S. et al. (2002). Association between presence of HLA-B*5701, HLA-DR7, and HLA-DQ3 and hypersensitivity to HIV-1 reverse-transcriptase inhibitor abacavir. Lancet. 359(9308):727-732.
	AL	Nassif, A., et al. (2002). Drug specific cytotoxic T-cells in the skin lesions of a patient with toxic epidermal necrolysis. J Invest Dermatol. 118(4):728-733.
	AM	Pirmohamed, M., and Park, B.K. (2003). Adverse drug reactions: back to the future. Br J Clin Pharmacol. 55(5):486-492.
	AN	Romphruk, A., et al. (2003). HLA-B*15 subtypes in the population of north-eastern Thailand. Eur J Immunogenet. 30(2):153-158.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	